REMARKS

This paper is responsive to the Examiner's Final Office Action of March 31, 2008. Applicants have hereby amended the Abstract and Claim 1. By way of summary, Claims 1-3 were and remain pending in this application. Reconsideration of the application in view of the foregoing amendments and following remarks is respectfully requested.

The specific changes to the abstract and any amended claims are shown by strikethrough or double bracketing for any deletions, and underlining for any insertions.

Amendments to the Abstract

As shown above, the Abstract of the Disclosure has been amended, to better reflect the claimed subject matter. Support for this amendment can be found in the Application as originally filed. No new matter has been introduced. Accordingly, Applicants respectfully request entry of this amendment.

Claims 1-3 are Patentable Over the Applied Combinations

The Examiner rejected Claims 1-3 under 35 U.S.C. § 103(a) as being obvious in view of the combination of (i) U.S. Patent No. 6,544,249 B1 to Yu et al. ("Yu") and U.S. Patent No. 6,827,700 B2 to Lynch et al. ("the Lynch patent"), and (ii) the Lynch patent and U.S. Patent No. 5,092,837 to Ritch et al. ("Ritch").

Applicants respectfully traverse these rejections and the Examiner's characterization of the cited references on the bases set forth below.

As shown above, Claim 1 has been amended for antecedent purposes only. This amendment does not alter the scope of the Claim.

Firstly, as discussed in the prior Response of January 10, 2008, the Lynch patent is not prior art to the present application. The pending claims have an effective filing date of April 14, 2000. In contrast, the disclosure of the Lynch patent has an effective filing date of April 26, 2000, and while the Lynch patent claims priority to a provisional application 60/131,030 (hereafter "the Lynch provisional"), that disclosure does not provide support for many features disclosed in the Lynch patent. The Examiner conceded to this on page 6 of the outstanding Office Action.

The Lynch provisional, at page 11, discloses a device and method for shunting aqueous fluid from the anterior chamber into Schlemm's canal. Only a T-shaped shunt device is disclosed with a radial tube (inflow portion) and a cross tube (outflow portion) with two arms extending generally perpendicularly from the radial tube in opposed directions. "The length of the cross tube is at least 3 mm," and the cross tube arms extend along the circumference of Schlemm's canal. Drainage through the device is non-axial.

The Lynch provisional, also at page 11, further discloses a specific method of inserting the disclosed shunt device. This is through an incision "at the limbus beneath the scleral flap. In other words, it is procedure commonly known as "ab-externo" (from the outside), as known in the art. The insertion method involves an intricate threading of the cross tube arms (outflow portion) into Schlemm's canal, particularly suited for the disclosed shunt device.

The Examiner asserted at page 3, lines 6-10 of the Office Action (emphasis added):

> Therefore, it would have been obvious to one of ordinary skill in the art to modify the ocular implant and applicator of Yu with the L-shaped orientation of Lynch **in order to anchor the implant in position** and allow the outflow portion to be oriented parallel to Schlemm's canal, allowing the implant to follow the natural shape of Schlemm's canal.

Applicants respectfully disagree with the Examiner's assertion. Yu already teaches anchoring as stated at column 6, lines 10-24 (emphasis added):

> Optionally, the microfistula tube 10 can be provided with one or more rearward pointing barbs (not shown), preferably located near the forward end 12 and on the outer surface of the microfistula tube 10. **These barbs would resist the unwanted rearward movement of the microfistula tube 10 following implantation.** The flared rear end 14 of the microfistula tube 10, and the generally tapered profile of the microfistula tube 10, **will resist unwanted forward movement of the microfistula tube 10.** The thickening of the rear end 14 of the microfistula tube 10 can be extended forward some distance **to further resist unwanted forward motion of the microfistula tube 10 after implantation.** This thickened portion of the rearward end 14 may be terminated more abruptly than shown in FIG. 1, **so that a substantially forward facing surface is provided for this purpose.**

Thus, one of ordinary skill in the art would not have a reason to modify Yu with the Lynch's T-shaped device, since Yu's tubular implant already has features that resist implant movement.

Moreover, Yu teaches away from a T-shaped shunt device as disclosed by the Lynch provisional, at least partially because Yu is concerned with the size of the corneal incision required to deliver the implant. Yu teaches the undesirability of large incisions, such as, 1 mm x 3 mm or even larger (see, column 1, lines approx. 24-27). As such, the drainage device of Yu employs a tubular structure (see, e.g., FIG. 1), with axial drainage, so that the corneal incision needed to introduce the device in the anterior chamber is minimized. Therefore, modifying Yu with the T-shaped shunt device of the Lynch provisional with a cross tube (outflow portion) with a length of at least 3 mm and non-axial drainage, would go against the teachings of Yu.

Furthermore, the Examiner's attention is directed to column 2, lines 61-65 of Yu, wherein Yu discloses that a tube adapted to form a passage to Schlemm's canal will preferably have an inner diameter of between 100 and 150 μm, and more preferably approximately 150 μm. Turning again to page 11 of the Lynch provisional, it is also disclosed that the radial tube (inflow portion) has "an internal dimension of 0.150 mm diameter," that is an inner diameter of 150 μm same as that disclosed by Yu.

Thus, both references have a tubular structure that is roughly the same size as the other. However, Yu does not teach any further tubular portions while the Lynch provisional discloses an additional cross tube (outflow portion). Given that the length of Lynch's cross tube is at least 3 mm, the size of the corneal incision needed to deliver such a large sized shunt device with the delivery system of Yu would be significantly larger than required by Yu, even if this shunt device has some capability of compaction due its flexibility. Accordingly, Applicants respectfully submit again that Yu teaches away from using a T-shaped shunt device as disclosed by the Lynch provisional.

Turning now to the applied combination with Ritch, the Examiner asserted at page 4, lines 8-12 of the Office Action (emphasis added):

> Therefore, it would have been obvious to one of ordinary skill in the art to combine the ocular implant of Lynch with the insertion method of Ritch in order to provide **a means for inserting an implant on the inner surface of the eye while puncturing as little tissue as possible.**

Applicants respectfully disagree with the Examiner's assertion. One of ordinary skill in the art would not make this combination, since the structure and size of the T-shaped shunt device disclosed by the Lynch provisional (as discussed above) would inherently lead to a larger

corneal incision size if combined with the implantation instrument of Ritch. More specifically, Ritch states at column 6, lines 52-54 and lines 63-67 respectively (emphasis added):

> The cannula 17 may have an **outer diameter in the range of about 1 mm and an inner diameter of 0.65 mm.**
>
> ...
>
> The flanges may have an overall maximum expanded diameter of approximately 1.25 mm **the overall diameter being approximately 0.75 mm in the compressed (cannula encompassed) condition.**

Applicants believe that it would not be possible to compact a T-shaped shunt device with a span of at least 3 mm to a dimension that would fit in Ritch's discloses cannula without compromising the structural integrity and operation of the device when implanted.

Moreover, Ritch teaches away from a combination of the disclosed implantation instrument with Lynch's shunt device. The implantation instrument (16) taught by Ritch has certain features that would render it inoperable with Lynch's shunt device, and which are particularly suited to deliver the insert (21), which provides axial drainage from the anterior chamber. For example, Ritch discloses that the implantation instrument has a filament (34) that is disposed within the insert drainage passage (36) during implantation (see, column 5, lines 58-63, and FIGS 4A and 4B). Ritch states at column 5, line 60 to column 6 line 2 the advantages of this arrangement:

> The inner end 35 of the filament 34 is disposed within and preferably frictionally engages within the drainage passage 36 formed through the insert member 21. **It will thus be observed that a degree of control of the position of the insert is achieved by virtue of the frictional connection between the filament 34 and insert 21.**
>
> The filament series [sic] **the additional function of assuring that the drainage aperture in the insert will not be clogged by tissue fragments during emplacement of the insert.**

The disclosed T-shaped Lynch shunt device fails to teach a central axial passage with openings at both ends, and in fact teaches openings at the ends of the T-shape.

Ritch further teaches away from a combination with Lynch's shunt device by requiring an "ab-interno" (from the inside), as referred to in the art, implantation procedure as opposed to the specific "ab-externo" (from the outside) disclosed by the Lynch provisional. At column 2, lines

6-7 Ritch refers to the "drawbacks inherent in surgical procedures of the conventional type (performed from the exterior)."

Thus, not only would one of ordinary skill in the art have no reason to combine the art applied by the Examiner, the references also teach away from the applied combinations.

Turning now to the specific claims, independent Claim 1 is directed to a glaucoma treatment kit and recites, *inter alia* (emphasis added):

> wherein a **long axis of a flow path of the inflow portion is disposed generally transversely to a long axis of a flow path of the outflow portion** when the implant is releasably held by the applicator.

As discussed above, on the bases of several reasons, the applied combinations of Yu and Ritch with the Lynch patent fail to render at least this structure obvious. Accordingly, Applicants submit that Claim 1 is patentable over the applied combinations.

Claims 2 and 3 depend from Claim 1 and are patentable for at least the same reasons that Claim 1 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 1-3 are in condition for allowance.

Double Patenting

The Examiner provisionally rejected Claims 1 and 2 on the ground of obviousness-type double patenting as being unpatentable over claims 1, 3 and 5 of co-pending U.S. Patent Application No. 11/121,584 (U.S. Patent Application Publication No. 2005/0192527 A1) to Gharib et al.

As noted in the prior Response of January 10, 2008, Applicants will file a Terminal Disclaimer when the provisional nonstatutory obviousness-type double patenting rejections are the only rejections remaining in the application, as provided at M.P.E.P. § 804, subsections I.B. Thus, Applicants respectfully request that the Examiner provide Applicants the opportunity to file a Terminal Disclaimer once allowable subject matter has been determined.

The Examiner also rejected Claims 1-3 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,780,164 B2 to Bergheim et al. in view of U.S. Patent No. 6,827,700 B2 to Lynch et al.

Though the Examiner refers to claims 1-9 of the '164 patent, this patent has only 6 claims. Moreover, Applicants do not properly understand the reasoning presented in the last paragraph on page 5 of the outstanding Office Action. For example, it is not clear what the Examiner means when he refers to "Claim 5 of the patent discloses an instrument for delivering implants ..." and "the application '213 claim 5" when trying to explain the double patenting rejection. Moreover, the Lynch '700 patent is not prior art to the subject matter claimed herein as explained above. **Applicants had requested clarification of this double patenting rejection in the prior Response of January 10, 2008, and respectfully do so again.**

On clarification of the above, Applicants will file a Terminal Disclaimer.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed	Attorney Docket No.
11/126,868	INJECTABLE TRANSFORMABLE IMPLANT AND METHODS THEREOF FOR OCULAR DISORDER TREATMENT	May 11, 2005	GLAUKO.1C3CP2
11/124,440	METHOD OF DELIVERING AN IMPLANT FOR TREATING AN OCULAR DISORDER	May 6, 2005	GLAUKO.1C4C2
11/121,584	IMPLANTS FOR TREATING OCULAR DISORDERS	May 4, 2005	GLAUKO.005C1C1
10/950,175	IMPLANT WITH INTRAOCULAR PRESSURE SENSOR FOR GLAUCOMA TREATMENT	September 24, 2004	GLAUKO.5C1CP1
11/598,542	IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	November 13, 2006	GLAUKO.011C1
12/111,033	SYSTEM FOR TREATING OCULAR DISORDERS AND METHODS THEREOF	April 28, 2008	GLAUKO.011C1C1
10/634,213	DEVICES AND METHODS FOR GLAUCOMA TREATMENT	August 5, 2003	GLAUKO.011CP1
11/836,106	DEVICES AND METHODS FOR GLAUCOMA TREATMENT	August 8, 2007	GLAUKO.11CP1C1
11/836,112	DEVICES AND METHODS FOR GLAUCOMA TREATMENT	August 8, 2007	GLAUKO.11CP1C2
11/084,314	INJECTABLE GLAUCOMA IMPLANTS WITH MULTIPLE OPENINGS	March 18, 2005	GLAUKO.11CP2CP1
11/083,713	OCULAR IMPLANTS WITH ANCHORS AND METHODS THEREOF	March 18, 2005	GLAUKO.011CP3
11/455,598	IMPLANT DELIVERY SYSTEM AND METHODS THEREOF FOR TREATING OCULAR DISORDERS	June 19, 2006	GLAUKO.017C1
11/455,391	GLAUCOMA STENT SYSTEM	June 19, 2006	GLAUKO.017C2

Serial Number	Title	Filed	Attorney Docket No.
11/332,746	FLUID INFUSION METHODS FOR OCULAR DISORDER TREATMENT	January 12, 2006	GLAUKO.020C1
10/667,580	OCULAR IMPLANT WITH ANCHOR AND MULTIPLE OPENINGS	September 22, 2003	GLAUKO.035A
10/860,785	COIL IMPLANT FOR GLAUCOMA TREATMENT	June 2, 2004	GLAUKO.051A
11/938,238	UVEOSCLERAL SHUNT AND METHODS FOR IMPLANTING SAME	November 9, 2007	GLAUKO.099A

Conclusion

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments may have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Applicants reserve the right to later present additional facts and arguments supporting the non-obviousness of the claimed subject matter should the Examiner not agree that the suggested combination of teachings is improper.

Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly. Also, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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